FastFacts

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User Fees and Drug Development

Introduction

Developing, testing and approving new prescription drugs is a long and expensive process. But when the U.S. Food and Drug Administration gets backlogged, and new medications are unnecessarily delayed, patients suffer.

That was the problem in the early 1990s, when policymakers pioneered a novel solution: user fees. Congress passed legislation allowing the FDA to collect user fees from pharmaceutical companies and apply the revenue toward speeding up the approval process. The approach worked so well that similar user-fee programs have since evolved to bolster the FDA's approval processes for medical devices, biosimilar medications and generic drugs.

Q: What are user fees?

FDA user fees are sums collected from the businesses and organizations that apply for FDA's approval and certification processes.

The first user-fee program, for new prescription drugs, was created by Congress in 1992. The FDA was instructed to use the revenue to bolster its budget to clear a backlog of unreviewed new drugs and establish a faster, more predictable timeline for new drug reviews going forward.

The system proved so effective that Congress has reauthorized the original program, the Prescription Drug User Fee Act, every five years since. It has also created additional user-fee programs for other sectors of the health care industry: for generic drugs, biosimilars, veterinary medicines, medical device manufacturers and even for certain health-related accrediting bodies.

Under the user-fee approach, the FDA drug review process has become faster, more transparent and more reliable. The old backlog is gone. The FDA has consistently met its stated goal of completing 90% of all application reviews within six-10 months.[1]

Q: Who makes decisions about user fees?

Congress reauthorizes the FDA's user-fee programs every five years. This gives everyone — from patients and clinicians to drug companies to policymakers themselves — plenty of lead time to share information and coordinate update efforts.

For instance, leading up to the 2022 reauthorization, the FDA began convening public meetings for stakeholders two years in advance. Pharmaceutical companies were able to show what worked and what needed improvement. Frontline health care providers helped identify areas of particular need. And patients educated policymakers about their firsthand experiences with specific diseases.

Final policy decisions about user fees are made by Congress in consultation with the FDA, but only after an inclusive and transparent process.

User-Fee Programs

User fees support the development of medications, devices and certain accreditations.


Novel Medications

Generics


Biologics


Biosimilars


Medical Devices


Veterinary Medications


Accreditation and Certification Entities

The FDA now approves about 95 first-time generics each year.

Q: Do user fees apply to generic drugs as well?

Yes, Congress created a user-fee program for generic drugs in 2012.

The goal was simple: to bring the benefits of the user-fee system to the generic drug market, which accounts for 90% of all U.S. prescriptions every year.[2] Generics, including complex generics, save patients money — more than $2.4 trillion between 2011 and 2020, according to one study.[3] But they also expand patient access to lifesaving medications, encourage competition in the pharmaceutical industry and drive down prices for prescription medicines all around.

The FDA's success with generic drug reviews underscores the benefits of the user-fee approach. Since 2018, 90% of generic drug applications have been reviewed on an accelerated timeline, and an average of 95 first-time generics have been approved each year.[4] Complex generics are not far behind, though steps still need to be taken to speed up their rate of review.

Q: How do user-fee programs involve patients?

The programs' clockwork, five-year review cycle allows patients' voices to be heard at every step in the process. Public listening sessions, meetings on Capitol Hill and coordination with national organizations allow patients to communicate both with policymakers in Washington and with other stakeholders.

The Patient-Focused Drug Development program, created in 2012, offers particular value for patients. In its first decade, the program has grown into an essential source of patient input in the FDA's drug approval system, including meetings, sophisticated statistical metrics and, since 2016, a formal role for patient advocacy groups in the process.[5]

Q: How have user fees expanded affordable treatment options?

Before the generics user-fee program was created in 2012, the FDA had a backlog of more than 2,500 generic drug applications. At the time, it took the FDA approximately 31 months to approve new generic medications, costing patients billions of dollars in potential savings.[6]

Once again, the user-fee approach worked. Today, the backlog is cleared. Almost all generic drug applications are reviewed in a timely manner. Between 2017 and 2021, the FDA approved more than 3,000 generic drugs — including some 1,300 for treating COVID-19 — and issued more than 50,000 individual communications to the pharmaceutical industry.[7]

Q: How can user-fee programs improve treatment access?

User-fee programs have accelerated the FDA's approval process for new, generic and biosimilar medicines. The FDA now typically processes new applications in six-10 months.

The agency is also exploring still more ways to expedite approval and access for patients. The new Split Real-Time Application Review pilot program, for example, could accelerate patient access and FDA-approval for new medications targeting unmet medical needs.[8]

Through programs like these, and the user-fee system itself, the FDA is building both the credibility and the capacity to deliver on its lifesaving mission.

Conclusion

User-fee programs have enabled the FDA to approve more new, generic, and biosimilar medications for 30 years now — and they are poised to continue doing so.

With the revenue provided by user fees, the FDA has the manpower to meet the explosive demand for new and generic medicines — and to complete its reviews on tight, predictable schedules. The process has also allowed policy to be made through an inclusive and transparent process. Congress and the FDA now hear from people across the health care system, including patients themselves, leading to greater collaboration and accountability.

Since the introduction of user fees to the generic drug approval process in 2012, the application backlog has disappeared. Almost 100 first-time generic drugs are being safely approved every year, and at a faster pace than ever before. The FDA's generic drug user-fee system is spurring competition throughout the pharmaceutical industry and, perhaps most importantly, lowering prices and expanding access for patients.

References

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ABOUT THE GENERICS ACCESS PROJECT

The Generics Access Project advocates for policies that promote generic competition and efficient approval of generic medicines.

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